

Bayer 10,258-HCL
100717-590
Le A 33 324 US-02

REMARKS

35 U.S.C. 112, second paragraph rejection

Claims 24-43 were rejected under this section for the following reasons (text from office action is repeated and answers to rejection immediately follow):

(1) Rejection Text:

"The definitions of R^3 - R^6 in claims 24 and 26 indicate that two of these radicals may form a ring 'which contain further heteroatoms'. What heteroatoms are permitted? Are they oxygen, nitrogen, and sulfur or is a metal or a halogen permitted? What is the size of the ring? Is there any limit? What other atoms are intended? How many additional non-carbon atoms may be present? For example in the passage spanning line 5, page 61 to line 2, page 62, Applicants describe the ring formed by R^3 and R^4 . Applicants use open language 'can be selected from the following nonexclusive list.' The following structures are five to seven-membered and contain a single nitrogen, sulfur, or oxygen atom. Is this all?"

Applicants' Answer:

MPEP 2111.01 states that "When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art." (see page 2100-48 from Feb. 2003 edition)

The term "heteroatom" is well known in the art and the size and scope of the atoms which are encompassed therein can be ascertained by one of ordinary skill in the art ("atom other than carbon"). It is further noted that even if "heteroatom" had no precise definition, MPEP 2173.05 states that "The fact that claim language, including term of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. [citations omitted] Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification."

The examiner's questions appear to show concerns about breadth of the claims. However, MPEP

Bayer 10,256-HCL
100717-590
Le A 33 324 US-02

2173.04 states that "Breadth of a claim is not to be equated with indefiniteness" (see also *in re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971)).

Although an enablement rejection was not made in this office action, even if a rejection had been made on breadth (i.e. scope of enablement - application of the *Wands*-factors), the state of the art with regard to heterocyclic chemistry is such that one of ordinary skill in the art would know which and how many heteroatoms could be used to form a heterocyclic ring for the situations represented by each of R^3 - R^6 (e.g. heterocyclic rings can be determined through CAS Registry files; *The Ring Index*, (publ. by American Chemical Society), 1960; etc.). MPEP 2164.01 (Test of Enablement) states "A patent need not teach, and preferably omits, what is well known in the art. [citations omitted]" - see page 2100-179 from Feb. 2003 edition.

With regard to the question of the size of the ring, the claim language for each of R^3 - R^6 is directed toward the formation of 4- to 6-membered ring systems and as such it is unclear why this would be considered to be indefinite.

(2) Rejection Text:

"The phrase 'alkynyl residue' occurs in claim 26 in the definition of radical R^2 . It occurs also in line 25, page 48 of the specification but is not further defined. Is the alkynyl radical, containing a carbon-to-carbon triple bond, intended?"

Applicants' Answer

The carbon-to-carbon triple bond is intended for this residue. However, it is believed that "alkynyl" is an equivalent to the term "alkynyl". If the examiner prefers the term "alkynyl", a supplemental response can be submitted upon request in the Advisory Action by the examiner.

35 U.S.C. 112, first paragraph rejection

Claims 35 and 36 were rejected for scope of enablement with regard to inhibiting angiogenesis. The applicants' request reconsideration of this rejection on two grounds.

Bayer 10,256-HCL
100717-590
Le A 33 324 US-02

First, the examiner appears to concede that the claimed invention would inhibit angiogenesis but would do so for mammals with below normal, normal or above normal angiogenesis activity and further states "The specification fails to teach any benefit to be gained from such actions." However, this appears to be sound more like a question of specific utility rather than enablement of the invention. Moreover, one of ordinary skill in the art would be able to determine when to apply the claimed method to a patient (i.e. when inhibition of angiogenesis is needed).

Second, it is well known that a determination for lack of enablement is a question of law based on underlying factual findings (*Id.* at 2100-179). It is also well known that "[t]he standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The *Wands* factors are disclosed in MPEP 2164.01(a) and include:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill in the art;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

As of this point, the examiner has not conveyed his factual findings as to why the claims are not deemed to be enabled and/or considered how these factual findings relate to the *Wands*-factors analysis for determining whether undue experimentation was necessary (see MPEP 2164.01(a)).

Therefore, it is believed that the rejection of claims 35 and 36 based on lack of enablement may be withdrawn.

Bayer 10,256-HCL
100717-590
Le A 33 324 US-02

Double Patenting Rejection

It is believed that the appropriate terminal disclaimers have already been filed with this application. If they have not been received, please indicate on the Advisory Action.

Closing

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

Norris, McLaughlin & Marcus, P.A.

By: Howard C. Lee
Howard C. Lee
Reg. No. 48,104

220 East 42nd Street
30th Floor
New York, New York 10017
(212) 808-0700

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (5 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 4 November 2003

By: Agata Gliniska
Agata Gliniska